

Patent Case: DX0757K

- 3 -

STATUS OF CLAIMS

Claims 16 and 22 have been cancelled. Claims 12, 13, 15, 17, 19, 23-27, 37 and 40 have been amended for greater clarity and consistency. Claim 41 has been added. Support for these claim amendments and added claim may be found throughout the specification and the originally filed claims. No new matter has been added by these claim amendments.

Applicants attach Appendix A with the newly revised claim set, primarily for the Examiner's convenience.

In addition, Applicants attach Appendix B a marked-up version of the changes made to the specification and claims by the current amendment entitled "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

REJECTIONS UNDER 35 U.S.C. § 101

Claim 19 stands rejected under 35 U.S.C. § 101, as allegedly being directed to non-statutory subject matter for reciting "a method of using."

Claim 19 has been amended to read as follows:

A method for producing a duplex nucleic acid, comprising contacting one strand of the nucleic acid of Claim 15 to a complementary strand, thereby producing said duplex.

In addition, the subject matter of Claim 19(b) has been incorporated into new Claim 41. New Claim 41 reads as follows:

A method for producing a polypeptide, comprising expressing the nucleic acid of Claim 15 in an isolated non-human host cell, thereby producing said polypeptide.

Claims 12 and 13 stand rejected under 35 U.S.C. § 101, as allegedly being directed to non-statutory subject matter for reciting "a host cell."

Claims 12 and 13 have been amended to read as follows:

12. An isolated non-human host cell or tissue comprising a recombinant nucleic acid of Claim 11.

13. The isolated non-human host cell of Claim 12, wherein said isolated non-human host cell is:
a) a prokaryotic cell;
b) a eukaryotic cell;
c) a bacterial cell;
d) a yeast cell;
e) an insect cell;
f) a mammalian cell;
g) a mouse cell; or
h) a primate cell.

Patent Case: DX0757K

- 4 -

Claims 11-19, 22-27, 37-40 stand rejected under 35 U.S.C. § 101, as allegedly lacking a specific and substantial asserted utility or a well established utility.

The claims are directed to a nucleic acid encoding a 7 transmembrane polypeptide BLRx. In addition to the sequence homology pointed out by the Examiner, the specification discusses the biological activity of BLRx, for example, on page 72, line 16 to page 73, line 33. Expression analysis data for BLRx in various tissues and cell types as well as under various conditions is compiled in Figure 6. The specification states "these results indicate that BLRx may play a role in wound healing, sclerotic processes, keloid formation, collagen synthesis, scleroderma, systemic sclerosis or in other biological process where these cell types are implicated." See page 73, lines 8-12. Furthermore, the specification reports *in vivo* wound healing studies. Expression data for BLRx during various phases of wound healing studies is presented in Figure 7. The specification states "BLRx expression is up-regulated during early wound healing, peaking at 12 hours. The results evidence that BLRx plays a role in wound healing." See page 73, lines 29-33. The specification also discusses the biological significance and utility of BLRx for the treatment of wounds, for example, on page 49, lines 12-25.

Applicants believe that the expression data disclosed in the specification supports the utility of the present claims and respectfully request withdrawal of this 35 U.S.C. § 101 rejection.

REJECTIONS UNDER 35 U.S.C. § 112, first paragraph

Claims 11-19, 22-27, 37-40 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking a substantial asserted utility or a well established utility. In other words, it has been allegedly that one skilled in the art would not know how to use the claimed invention.

As noted above, Applicants point out that the specification discusses the utility of BLRx for the treatment of wounds. Applicants contend that the specification provides sufficient support for how to use the present invention, for example, on page 49, line 26 to page 53, line 36.

Based on the substantial asserted utility and the guidance on how to use the present invention, Applicants respectfully request withdrawal of this 35 U.S.C. § 112, first paragraph rejection.

Further note, that although Claims 22 and 23 had previously recited language directed to homology, Claim 22 has been cancelled and Claim 23 has been amended. Claim 23 now depends on Claim 11 and no longer recites language directed to homology.

Patent Case: DX0757K

- 5 -

REJECTIONS UNDER 35 U.S.C. § 112, first paragraph

Claims 22 and 23 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking sufficient written description to reasonably convey to one skilled in the art, that at the time the application was filed, the inventors had possession of the claimed invention.

As noted above, Claim 22 has been cancelled. Claim 23 has been amended so that it now depends on Claim 11 and no longer recites any language directed to homology. In light of these amendments, Applicants believe the written description requirement is met and respectfully request withdrawal of this 35 U.S.C. § 112, first paragraph rejection.

Claims 22-27 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for a peptide as set forth in Claims 22 and 23. But, the Examiner points out that the specification is enabling for a nucleic acid encoding a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 8.

As noted above, Claim 22 has been cancelled. Claim 23 has been amended so that it now depends on Claim 11 and no longer recites any language directed to homology. In addition, Claims 24-27 have been amended so that they are dependent on Claim 11. Consequently, Claims 23-27 are directed to a nucleic acid encoding a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 8.

In light of these claim amendments and the Examiner's statement above, Applicants believe the enablement requirement is met and respectfully request withdrawal of this 35 U.S.C. § 112, first paragraph rejection.

REJECTIONS UNDER 35 U.S.C. § 112, second paragraph

Claims 15-19, 22-27 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Claim 22 has been cancelled.

Claim 23 no longer recites the term "about." Claims 23-27 are no longer dependent on Claim 22 but are now dependent on Claim 11.

Claim 15 (from which Claims 18-19 depend) has been amended to specify the concentration of salt for the wash conditions.

Claim 16 has been cancelled.

Claim 17 has been amended as an independent claim.

Applicants believe the above amendments render the present claims clear to a skilled artisan and respectfully request withdrawal of this 35 U.S.C. § 112 rejection.

Patent Case: DX0757K

- 6 -

REJECTIONS UNDER 35 U.S.C. § 102

Claims 15-17 and 19 stands rejected under 35 U.S.C. § 102 as allegedly lacking novelty. In particular, Claims 15-17 and 19 stand rejected under 35 U.S.C. 102(b) as being anticipated by Matsuoka *et al.* (1993).

Matsuoka *et al.* describes a cDNA and corresponding amino acid sequence of a G-protein coupled receptor expressed in mammalian taste tissue.

Claim 16 has been cancelled. Claim 15 (from which Claims 18 and 19 depend) now reads as follows:

15. A nucleic acid which:

- a) hybridizes under wash conditions of 55° C and 500 mM salt to SEQ ID NO: 7; and
- b) exhibits identity over a stretch of 75 nucleotides to SEQ ID NO: 7.

Similarly, Claim 17 has been amended and now reads as follows:

17. A nucleic acid which:

- a) hybridizes under wash conditions of 65° C and 150 mM salt; and
- b) exhibits identity over a stretch of 75 nucleotides to SEQ ID NO: 7.

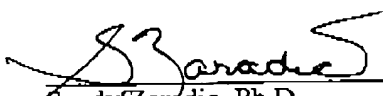
As shown in the sequence comparison provided by the Examiner, Matsuoka *et al.* does not describe a nucleic acid that encodes a polypeptide exhibiting a length of more than 24 amino acids. It thus appears that Matsuoka *et al.* does not describe a nucleic acid that exhibits a stretch of 75 nucleotides as recited in Claims 15 and 17. Consequently, Applicants respectfully request withdrawal of this 35 U.S.C. § 102 rejection.

CONCLUSION

Applicants believe that the foregoing amendments and arguments place this application now in condition for allowance. Early and favorable action allowing pending claims 11-15, 17-19, 23-27, and 37-41 is respectfully solicited.

Respectfully submitted,

SCHERING-PLOUGH CORPORATION
Patent Department, K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, New Jersey 07033-0530
Fax: 908-298-5388


Sandy Zaradic, Ph.D.
Reg. No. 45,997
Patent Agent for Applicants
(908) 298-7221

WHAT IS CLAIMED IS:

11. An isolated or recombinant nucleic acid encoding a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 8.
12. An isolated non-human host cell or tissue comprising a recombinant nucleic acid of Claim 11.
13. The isolated non-human host cell of Claim 12, wherein said isolated non-human host cell is:
- a) a prokaryotic cell;
 - b) a eukaryotic cell;
 - c) a bacterial cell;
 - d) a yeast cell;
 - e) an insect cell;
 - f) a mammalian cell;
 - g) a mouse cell; or
 - h) a primate cell.
14. A kit comprising said nucleic acid of Claim 11, and:
- a) a compartment comprising said nucleic acid;
 - b) a compartment further comprising a polypeptide of SEQ ID NO: 8; and/or
 - c) instructions for use or disposal of reagents in said kit.
15. A nucleic acid which:
- a) hybridizes under wash conditions of 55° C and 500 mM salt to SEQ ID NO: 7; and
 - b) exhibits identity over a stretch of 75 nucleotides to SEQ ID NO: 7.
17. A nucleic acid which:
- a) hybridizes under wash conditions of 65° C and 150 mM salt; and
 - b) exhibits identity over a stretch of 75 nucleotides to SEQ ID NO: 7.
18. A kit comprising said nucleic acid of Claim 15, and:
- a) a compartment comprising said nucleic acid;
 - b) a compartment further comprising a polypeptide of SEQ ID NO: 8; and/or
 - c) instructions for use or disposal of reagents in said kit.
19. A method for producing a duplex nucleic acid, comprising contacting one strand of the nucleic acid of Claim 15 to a complementary strand, thereby producing said duplex.
23. The nucleic acid of Claim 11, wherein the nucleic acid comprises the nucleotide sequence set forth in SEQ ID NO: 7.

Appendix A**Applicant: Hedrick *et al.*; Serial No.: 09/910,695; Filed: July 20, 2001****Page 1 of 2**

24. A recombinant vector comprising:
a) a nucleic acid according to Claim 11; and
b) control elements that are operably linked to said nucleic acid whereby a coding sequence within said nucleic acid can be transcribed and translated in a host cell, and at least one of said control elements is heterologous to said coding sequence.
25. An isolated non-human host cell transformed with the recombinant vector of Claim 24.
26. A method for producing a recombinant polypeptide comprising:
a) providing a population of isolated non-human host cells according to Claim 25; and
b) culturing said population of cells under conditions whereby a polypeptide encoded by the coding sequence present in said recombinant vector is expressed.
27. A method for expressing a recombinant polypeptide comprising:
a) transforming a host cell with the recombinant vector of Claim 24; and
b) causing expression of a polypeptide encoded by the coding sequence present in said recombinant vector.
37. An isolated or recombinant nucleic acid which comprises a nucleic acid encoding an polypeptide comprising a 27 amino acid fragment of the amino acid sequence set forth in SEQ ID NO: 8.
38. A kit comprising:
a) the isolated or recombinant nucleic acid of Claim 37 in a compartment; and
b) instructions for use or disposal of reagents in said kit.
39. An expression vector which comprises the isolated or recombinant nucleic acid of Claim 37.
40. An isolated non-human host cell transformed with the expression vector of Claim 39.
41. A method for producing a polypeptide, comprising expressing the nucleic acid of Claim 15 in an isolated non-human host cell, thereby producing said polypeptide.

Appendix A**Applicant: Hedrick *et al.*; Serial No.: 09/910,695; Filed: July 20, 2001****Page 2 of 2**

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

On page 1 and page 84,

~~MAMMALIAN CHEMOKINES; RECEPTORS; REAGENTS; USES~~
7 TRANSMEMBRANE RECEPTOR FAMILY MEMBER BLRX

IN THE CLAIMS

12. ~~An isolated non-human host cell~~ or tissue comprising a recombinant nucleic acid of Claim 11.

13. The isolated non-human host cell of Claim 12, wherein said isolated non-human host cell is:

- a) a prokaryotic cell;
- b) a eukaryotic cell;
- c) a bacterial cell;
- d) a yeast cell;
- e) an insect cell;
- f) a mammalian cell;
- g) a mouse cell; ~~or~~
- h) a primate cell; ~~or~~
- i) ~~a human cell.~~

15. A nucleic acid which:

- a) hybridizes under wash conditions of ~~45° C and less than 700 mM~~ 55° C and 500 mM salt to SEQ ID NO: 7; ~~or and~~
- b) exhibits identity over a stretch of ~~30~~ 75 nucleotides to SEQ ID NO: 7.

~~16. The nucleic acid of Claim 15, wherein:~~

- ~~a) said wash conditions are at 55° C and/or 500 mM salt; or~~
- ~~b) said identity is over at least 55 nucleotides.~~

17. ~~The~~ A nucleic acid of Claim 16, ~~wherein which:~~

- a) hybridizes under said wash conditions ~~are at~~ of 65° C and 150 mM salt; or and
- b) ~~said identity is over at least~~ exhibits identity over a stretch of 75 nucleotides to SEQ
ID NO: 7.

19. ~~A method of using for said nucleic acid of Claim 15:~~

- ~~a) to produce~~ producing a duplex nucleic acid, comprising contacting one strand of the nucleic acid of Claim 15 to ~~the~~ a complementary strand, thereby producing said duplex; ~~or~~
- ~~b) to produce a polypeptide, comprising expressing said nucleic acid in a host cell, thereby producing said polypeptide.~~

~~22. An isolated nucleic acid encoding a polypeptide comprising the amino acid sequence set~~

Appendix B

Applicant: Hedrick *et al.*; Serial No.: 09/910,695; Filed: July 20, 2001

Page 1 of 2

~~forth in SEQ ID NO: 8, or a polypeptide having at least about 80% sequence homology thereto.~~

23. The nucleic acid of Claim ~~22~~ 11, wherein the nucleic acid comprises the nucleotide sequence set forth in SEQ ID NO: 7, ~~or a nucleic acid having at least about 80% sequence homology thereto.~~

24. A recombinant vector comprising:

- a) a nucleic acid according to Claim ~~22~~ 11; and
- b) control elements that are operably linked to said nucleic acid whereby a coding sequence within said nucleic acid can be transcribed and translated in a host cell, and at least one of said control elements is heterologous to said coding sequence.

25. An isolated non-human host cell transformed with the recombinant vector of Claim 24.

26. A method ~~of for~~ producing a recombinant polypeptide comprising:

- a) providing a population of isolated non-human host cells according to Claim 25; and
- b) culturing said population of cells under conditions whereby a polypeptide encoded by the coding sequence present in said recombinant vector is expressed.

27. A method ~~of for~~ expressing a recombinant polypeptide comprising:

- a) transforming a host cell with the recombinant vector of Claim ~~22~~ 24; and
- b) causing expression of a polypeptide encoded by the coding sequence present in said recombinant vector.

37. An isolated or recombinant nucleic acid which comprises a nucleic acid encoding an ~~antigenic~~ polypeptide comprising:

- a) ~~an 8 amino acid fragment of the amino acid sequence set forth in SEQ ID NO: 8;~~
- b) ~~a 12 amino acid fragment of the amino acid sequence set forth in SEQ ID NO: 8; or~~
- e) a 27 amino acid fragment of the amino acid sequence set forth in SEQ ID NO: 8.

40. An isolated non-human host cell transformed with the expression vector of Claim 39.

41. (new) A method for producing a polypeptide, comprising expressing the nucleic acid of Claim 15 in an isolated non-human host cell, thereby producing said polypeptide.